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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

CALIFORNIA STEM CELL TREATMENT CENTER, INC., *et al.*

Defendants.

No. 5:18-CV-01005-JBG-KKx

PLAINTIFF'S NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT

Hearing Date: August 5, 2019
Hearing Time: 9:00 a.m.
Courtroom: Riverside Courthouse
3470 Twelfth Street
Riverside, CA 92501
Courtroom 1, 2nd Floor

Hon. Jesus G. Bernal

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on August 5, 2019, at 9:00 a.m., or as soon thereafter as this matter may be heard in the above-entitled Court, Plaintiff United States of America will, and hereby does, move this Court pursuant to Federal Rule of Civil Procedure 56 for an order granting summary judgment in favor of Plaintiff and against Defendants California Stem Cell Treatment Center, Inc., Cell Surgical Network Corporation, and individuals Elliot B. Lander, M.D., and Mark Berman, M.D., as to all claims alleged in Plaintiff's Complaint for Permanent Injunction. The motion will be made in the Riverside Courthouse before the Honorable Jesus G. Bernal, United States District Judge, located at 3470 Twelfth Street, Riverside, CA 92501.

Plaintiff's motion is made on the grounds that there is no genuine issue of material fact as to whether Defendants violate the Federal Food, Drug, and Cosmetic Act ("FDCA") by manufacturing and delivering unapproved experimental drugs, purportedly to treat a variety of serious diseases and conditions. The undisputed evidence and Defendants' admissions demonstrate that Defendants' products are both adulterated and misbranded under the FDCA. The United States is thus entitled to judgment as a matter of law, and to a permanent injunction barring Defendants from manufacturing and delivering their unlawful products.

This motion is made upon this notice; the Memorandum of Points and Authorities, the Statement of Undisputed Facts and Conclusions of Law and the evidence cited therein, the Proposed Order of Permanent Injunction and Proposed Judgment, the Declarations of Christopher C. Joneckis, Doran L. Fink, Larissa Lapteva, Randa F. Melhem, Natalie N. Sanders, Karlton T. Watson, and Carolyn Yong, and all pleadings, records, and other documents on file with the Court in this action, and upon such oral argument and evidence as may be presented in connection with the hearing of this motion. This motion is made following the conference of counsel pursuant to Local Rule 7-3, which took place on June 28, 2019.

DATED: July 8, 2019.

Respectfully Submitted,

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EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

CALIFORNIA STEM CELL TREATMENT CENTER, INC., *et al.*

Defendants.

No. 5:18-CV-01005-JBG-KKx

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFF'S NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION

Defendants, including California Stem Cell Treatment Center ("CSCTC"), manufacture unproven, experimental drugs and administer them to patients, purportedly to treat a wide range of diseases and conditions, such as cancer, arthritis, stroke, multiple sclerosis ("MS"), and chronic obstructive pulmonary disease ("COPD"). Defendants recover adipose tissue (fat) from a patient and, without FDA license or approval, process that tissue to obtain cellular components known as stromal vascular fraction or "SVF." Defendants then administer the SVF along with another drug component such as saline (the "SVF product") into different parts of the patient's body. In an especially dangerous form of experimentation, Defendants combined SVF with Vaccinia Vaccine, Live, a smallpox vaccine for persons at high risk for smallpox infection, and administered the product (the "SVF/Vaccinia product") to vulnerable patients with advanced-stage cancers. Even when used appropriately, Vaccinia vaccine comes with the most severe form of U.S. Food and Drug Administration ("FDA") warning, a "black box warning," for risk of serious or life-threatening swelling of the heart tissues, brain, or spinal cord.

Defendants' conduct and their drug products—which include the SVF product, the SVF/Vaccinia product, and an expanded SVF product (collectively, the "CSCTC products")—violate the Federal Food, Drug, and Cosmetic Act ("FDCA") in two basic ways. First, it is illegal to manufacture and sell drugs that are produced without adherence to FDA's current good manufacturing practice ("CGMP") requirements.[1] Such drugs are adulterated. *See* 21 U.S.C. § 351(a)(2)(B). FDA inspections of CSCTC facilities revealed serious and obvious CGMP violations, including Defendants' failure to aseptically process their CSCTC products to prevent microbiological contamination or test the products for sterility and for the presence of endotoxins which can cause fevers and other health complications. Because Defendants' CSCTC products are not manufactured, processed, packed, or held in compliance with CGMP, they are adulterated.

[1] CGMP requirements are designed to ensure that drugs (including biological products) have the identity, strength, quality, purity, and other attributes for safe and effective use.

Second, it is illegal to manufacture and sell drugs that lack appropriate labeling or that pose a danger to health when used as intended. Such drugs are misbranded. Defendants' CSCTC products are misbranded under 21 U.S.C. § 352(f)(1), because their labeling does not bear adequate directions for use and lacks critical required information, such as indications for use, dosages, and routes of administration. Indeed, it is impossible to draft adequate directions for use of the CSCTC products because there is no scientifically valid evidence to show that they are safe or effective for any indication. The CSCTC products are also misbranded under 21 U.S.C. § 353(b)(4) because they are prescription drugs and their labels fail to bear the "Rx Only" symbol. Moreover, Defendants' SVF/Vaccinia product is misbranded under 21 U.S.C. § 352(j) because the manner in which it is used makes it dangerous to health.

Defendants do not dispute the evidence of these violations. They admit they use or have used the CSCTC products to address patients' symptoms of neurological, autoimmune, orthopedic, and degenerative diseases and conditions, which makes them "drugs" under the FDCA. They admit the CSCTC products do not comply with CGMP, which makes them adulterated. And they admit the relevant facts regarding CSCTC product labeling which makes them misbranded.

But rather than comply with the law, Defendants misread two FDA regulatory provisions to argue that the FDCA's basic legal requirements do not apply to them and their experimental drugs. In particular, Defendants claim that their establishments are excepted from FDA regulation under 21 C.F.R. §1271.15(b) (the "same surgical procedure exception"). They also claim that their CSCTC products are not regulated as drugs or biological products because they meet the criteria at 21 C.F.R. § 1271.10(a), which applies to products that are, among other things, minimally manipulated and for homologous use only. Both arguments fail for the reasons detailed below. Indeed, the United States District Court for the Southern District of Florida fully rejected these same arguments in a recent decision against another firm that illegally manufactured similar adipose-derived SVF products in violation of the FDCA. *See* Order on Mots. for Summ. J., *United States*

v. US Stem Cell Clinic, LLC, No. 18-cv-61047 (S.D. Fla. June 3, 2019), ECF No. 73 ("*US Stem Cell Order*").[2] The same result should apply here.

Because the material facts are not in dispute and Defendants plainly violate the FDCA, the Government is entitled to summary judgment. Defendants do not simply move adipose tissue from one place in a patient's body to another. They instead manufacture unapproved new drugs that are both adulterated and misbranded. There is no scientifically valid evidence that Defendants' products are safe or effective, and Defendants' marketing gives unsubstantiated hope to people suffering from serious and sometimes life-threatening conditions. Moreover, Defendants' products have been associated with adverse events, such as serious infections that required hospitalization. Defendants' willingness to treat cancer patients with a product containing vaccinia virus—an active immunization against smallpox disease for persons at high risk for smallpox infection—not only put the patients at risk, but also represented a risk to the public health because people in close contact with those patients could have been infected with live virus. Permanent injunctive relief is necessary to stop Defendants' ongoing violations and to protect the public health.

II. STATUTORY AND REGULATORY FRAMEWORK

The FDCA's overriding purpose is to protect the public health. *See United States v. Dotterweich*, 320 U.S. 277, 280-81 (1943). Consistent with that purpose, the FDCA's adulteration and misbranding provisions are designed to ensure that products regulated by FDA are safe, effective, and properly labeled. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133-34 (2000); *United States v. Various Articles of Drugs*, 83 F. Supp. 882, 884-85 (D.D.C. 1949); *see also* 21 U.S.C. § 393(b)(2) (discussing FDA's

[2] The legal issues presented in this case are nearly identical to those presented in *US Stem Cell*, a parallel civil injunctive action that the United States filed on the same day as the instant case. The same law firm represents the defendants in both the Florida and California cases, and defendant US Stem Cell Clinic's expert witness was Dr. Elliot Lander, one of the named Defendants in the instant case. *See United States v. US Stem Cell Clinic, LLC*, No. 18-cv-61047 (S.D. Fla. 2019), ECF Nos. 45 and 45-2. A copy of the court's order is attached as Exhibit 1 to the Declaration of Natalie N. Sanders In Support of Plaintiff's Motion for Summary Judgment ("Sanders Decl.").

mission). Under the statute, a drug is adulterated and misbranded unless it complies with the requirements of 21 U.S.C. §§ 351, 352, and 353, as discussed below.

A. Drugs Under the FDCA

The CSCTC products are "drugs" within the meaning of the FDCA. An article is a "drug" and subject to the FDCA if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or is "intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(B) & (C). Thus, whether any particular article is a drug depends on its "intended use." *See Whitaker v. Thompson*, 353 F.3d 947, 953 (D.C. Cir. 2004) (classification as a "drug" under the FDCA "turns on the nature of the claims advanced on its behalf"); *United States v. Writers & Research, Inc.*, 113 F.3d 8, 11 (2d Cir. 1997) ("[I]f an article is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man it is defined as a drug."). "[I]t is well established that the 'intended use' of a product, within the meaning of the [FDCA], is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source." *Action on Smoking & Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980) (internal citations omitted); *see* 21 C.F.R. § 201.128.

The FDCA prohibits taking any action with respect to a drug "if such act is done while such article is held for sale . . . after shipment in interstate commerce and results in such article being adulterated or misbranded." 21 U.S.C. § 331(k). Under the FDCA, a drug is adulterated if "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with [CGMP] to assure that such drug meets the requirements of [the FDCA] as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C. § 351(a)(2)(B); *see* 21 C.F.R. Parts 210-211 (drugs); 21 C.F.R. Parts 600-680 (additional standards for biological products). A drug is misbranded under the FDCA "unless its labeling bears adequate directions for use" and the drug does not fall within a regulatory exemption from that requirement. 21 U.S.C. § 352(f)(1); *see* 21 C.F.R. § 201.5. A drug

is also misbranded if it is a prescription drug and its label fails to bear the "Rx Only" symbol, 21 U.S.C. § 353(b)(4)(A), or if the manner in which it is used makes it dangerous to health, 21 U.S.C. § 352(j).

B. Biological Products Under the PHSA

In addition to being drugs under the FDCA, Defendants' CSCTC products are also "biological products" subject to the requirements of the Public Health Service Act ("PHSA"), 42 U.S.C. § 262. A "biological product" includes any "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or *analogous product* . . . , applicable to the prevention, treatment, or cure of a disease or condition of human beings." *Id.* § 262(i) (emphasis added). A product may be both a drug and a biological product. *See, e.g.*, *United States v. Regenerative Scis., LLC*, 741 F.3d 1314, 1319 (D.C. Cir. 2014) ("Both of these wide-ranging definitions clearly apply to the [appellants' stem cell product], an article derived mainly from human tissue"); *United States v. Loran Med. Sys., Inc.*, 25 F. Supp. 2d 1082, 1084-86 (C.D. Cal. 1997) (cell product made from neonatal rabbit and human fetal cells was a drug and a biological product).

A product licensed under the PHSA is not required also to have an approved new drug application ("NDA") under the FDCA; in every other respect, however, the FDCA applies. 42 U.S.C. § 262(j). Thus, although the fact that a drug can also be a biological product may affect the applicability of certain statutory and regulatory requirements for approval, it does not exempt the product from other FDCA provisions, including provisions applicable to the adulteration and misbranding of drugs in this case.

C. Regulation of "HCT/P's"

Regulations promulgated under the PHSA (and codified in Part 1271 of Title 21 of the Code of Federal Regulations) apply to human cells, tissues, or cellular or tissue-based products, known as "HCT/P's." 21 C.F.R. § 1271.3(d) (defining HCT/P's as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient."). Certain HCT/P's that meet

four specific criteria at 21 C.F.R. § 1271.10(a) can be effectively regulated by controlling the communicable disease risks they present. These HCT/P's, sometimes referred to as "361 HCT/P's," are regulated solely under section 361 of the PHSA and the HCT/P regulations (21 C.F.R. Part 1271), even if such HCT/P's would otherwise meet the definitions of "drug" or "biological product." The regulations also identify certain circumstances under which an establishment is excepted from FDA's HCT/P regulations. *See*, *e.g.*, 21 C.F.R. § 1271.15(b) (the "same surgical procedure" exception). Unless an HCT/P meets all four of the criteria in 21 C.F.R. § 1271.10(a) for regulation solely under section 361 of the PHSA and the Part 1271 regulations—or unless one of the exceptions in 21 C.F.R. § 1271.15 applies (such as the "same surgical procedure" exception raised by Defendants)—the HCT/P is regulated as a drug, device, and/or biological product under the PHSA and/or the FDCA and is subject to the FDCA's adulteration and misbranding provisions. *See* Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. 5447, 5449 (Jan. 19, 2001) (hereinafter, "Final Registration Rule"); 21 C.F.R. §§ 1271.15 & 1271.20.

As set forth below, Defendants' CSCTC products do not meet all four of the Section 1271.10(a) criteria and, thus, are not eligible for regulation solely under section 361 of the PHSA and 21 C.F.R. Part 1271. Nor does the same surgical procedure exception or any other Section 1271.15 exception apply. Thus, Defendants are in direct violation of their legal obligations, and summary judgment is appropriate.

III. STATEMENT OF UNDISPUTED FACTS

A. The Defendants

Defendant CSCTC is a California professional corporation founded in 2010, with its principal place of business located in Rancho Mirage, California ("CSCTC Rancho Mirage"), and a second establishment located in Beverly Hills, California ("CSCTC Beverly Hills"), within the jurisdiction of this Court. Statement of Undisputed Facts ("SUF") ¶ 1.

Defendant Elliot B. Lander, M.D., a board-certified urologist and surgeon, is the

co-owner and Co-Medical Director of CSCTC. He is the most responsible individual at CSCTC Rancho Mirage and performs his duties there, within the jurisdiction of this Court. SUF ¶ 3. He manages employees at CSCTC Rancho Mirage where his activities include recovering adipose tissue from patients and manufacturing CSCTC products, which Defendants characterize as performing procedures. *Id.* Dr. Lander is the co-owner and Co-Medical Director of Defendant Cell Surgical Network ("CSN"). *Id*. He is also the co-owner of Cells On Ice, Inc., which has assisted in the recovery of adipose tissue sent outside of the State of California for manufacture into the expanded SVF product. *Id*.

Defendant Mark Berman, M.D., a board-certified cosmetic surgeon, is the co-owner and Co-Medical Director of CSCTC. SUF ¶ 4. He performs his duties at CSCTC Beverly Hills, within the jurisdiction of this Court, and is the most responsible individual at CSCTC Beverly Hills where his activities include recovering adipose tissue from patients and manufacturing CSCTC products, which Defendants characterize as performing procedures. *Id*. Dr. Berman is the co-owner and Co-Medical Director of Defendant CSN and co-owner of Cells On Ice, Inc. *Id*.

Defendant CSN is a California corporation founded by Defendants Berman and Lander in 2012 that is registered to do business at the same address as CSCTC Rancho Mirage, in California and within the jurisdiction of this Court. SUF ¶ 5. CSN operates a one-employee warehouse in Palm Desert, California, within the jurisdiction of this Court, from which equipment and supplies are shipped to CSN affiliates. *Id*.

Defendant CSN approves doctors to become affiliates or licensees for Defendants' network. SUF ¶ 30. CSN affiliates are required "to complete training" regarding what Defendants characterize as their SVF surgical procedure. *Id*. Once approved for inclusion in the network, CSN affiliates purchase supplies from CSN. *Id*. CSN affiliates are "required to comply with" CSN's "*Guidelines for Affiliates*," which states that an affiliate "must" "reasonably follow price guidelines to avoid competition for patient enrollment within the network," register patients into the CSN Database, and use standardized forms, including specific consent forms for patient care and data collection. SUF ¶ 31. CSN's

Guidelines for Affiliates also describes that affiliates have limited permission to use CSCTC and CSN logos. SUF ¶ 32.

B. The CSCTC Products

CSCTC manufactures, or has caused to be manufactured, several adipose (fat) derived CSCTC products, including: (1) the SVF product, which contains what is referred to as "stromal vascular fraction" manufactured from a patient's adipose tissue; (2) the SVF/Vaccinia product, which combines SVF and Vaccinia Vaccine, Live (*i.e.*, live smallpox vaccine);[3] and (3) the expanded SVF product, which has been expanded in culture (*i.e.*, an environment that encourages cell growth) for CSCTC by a third party. *See* SUF ¶ 2; *see also* 21 C.F.R. § 1271.3(e) (defining "manufacture" to include, without limitation, "any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor").[4]

Production of the CSCTC products containing SVF involves the recovery of adipose tissue from patients in dedicated operating rooms in CSCTC's Rancho Mirage and CSCTC Beverly Hills facilities. SUF ¶ 9. The tissue recovery is accomplished by a mini-liposuction procedure, whereby a cannula is used to recover adipose tissue through an incision commonly made in the patient's posterior flank. *Id*.

Defendants subject the recovered adipose tissue to numerous steps through which

[3] Last year, a court of this District found the vials of ACAM2000 Vaccinia Vaccine, Live used to manufacture Defendants' SVF/Vaccinia product to be misbranded drugs within the meaning of the FDCA, 21 U.S.C. §§ 352(f)(1) and 352(j). *United States v. Five Articles of Drug, ACAM2000, Vaccinia Vaccine, Live*, 8:17-CV-01449 (C.D. Cal. Mar. 20, 2018), ECF No. 27. Under the Default Judgment of Forfeiture entered in that case, the Defendants' interest in the seized Vaccinia Vaccine was forfeited to the Government. *Id*. The seized vials were misbranded because, as components of an SVF/Vaccinia product, they lacked adequate directions for use and were dangerous to health. *Id*.

[4] Defendants disagree with the Government's characterization of their production of the CSCTC products as a "manufacturing" process that results in a "product," but admit to the underlying factual assertions, which are in paragraphs 5, 9 and 10 of the Complaint. *See* Ans. ¶¶ 5, 9 and 10. Defendants' disagreement over the characterizations of the manufacturing process is immaterial to the resolution of this case. The parties agree about the steps of the process. SUF ¶¶ 9-10. And the fact that the process results in a "drug" as defined by the FDCA is established as a matter of law (based on undisputed facts). *See* Argument, Section A *infra*.

many components of the tissue are broken down and discarded. SUF ¶ 10. The process involves the addition of a solution of an enzyme to isolate cell components through enzymatic digestion. *Id*. It also includes an incubation period, several steps using a washing solution (5% Dextrose in Lactated Ringer's Injection), and filtration. *Id*. Manufacturing employs various types of equipment, including a specialized SVF processing device identified as the "Time Machine," syringes, plungers, stoppers, adapters, and a filter. *Id*. Among other things, Defendants' processing removes the adipocytes and the reticular fiber network of the adipose tissue. SUF ¶¶ 15-17. The processing also alters the tissue's physical properties, such as their utility to provide cushion and support. SUF ¶ 15; Yong Decl. ¶¶ 38-39.

Defendants have used their SVF/Vaccinia product as an experimental treatment for patients suffering from a variety of advanced-stage cancers and was administered to patients intravenously or directly into patients' tumors. SUF ¶ 27. Vaccinia Vaccine, Live, is also known by its proprietary name ACAM2000. ACAM2000 is an FDA-approved biological product for active immunization against smallpox disease only for persons determined to be at high risk for smallpox infection. SUF ¶ 26. The vaccine's labeling is required to display a "black box warning" designed to call attention to serious or life-threatening product risk, including swelling of the heart tissues, brain, or spinal cord. *Id.*; *see* 21 C.F.R. § 201.57(c)(l).

For their expanded SVF product, Defendants sent recovered adipose tissue to a firm outside of California for production into SVF, which then was expanded in culture. SUF ¶ 29. The expanded SVF products subsequently were returned in interstate commerce to CSCTC's Rancho Mirage and Beverly Hills facilities and administered to Defendants' patients, who may pay thousands of dollars to receive a single product. SUF ¶¶ 29, 25.

CSCTC products are intended for autologous use in patients (SUF ¶ 6), which refers to the "implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered." 21 C.F.R. § 1271.3(a). CSCTC products are administered to patients using a variety of methods, including

intravenously; injection into specific areas of the body, including an area around the brain; and via a nebulizer. SUF ¶ 8. CSCTC products are administered at CSCTC Rancho Mirage and CSCTC Beverly Hills, and at other locations such as a radiologist's office in Indian Wells, California. *Id.*

Defendants' CSCTC products are not licensed or approved by FDA. SUF ¶ 34. There are not now, nor have there ever been, any approved NDAs filed with FDA pursuant to 21 U.S.C. § 355(b) or (j) for the CSCTC products. SUF ¶ 35. There are not now, nor have there ever been, any approved biologics license applications filed with FDA pursuant to 42 U.S.C. § 262 for the CSCTC products. *Id.* No investigational new drug application ("IND") under 21 U.S.C. § 355(i) is currently in effect for any of the CSCTC products. SUF ¶ 36. Labeling on the CSCTC products lacks indications for use, dosages, routes of administration, and side effects; neither does it identify the products as "Rx only." SUF ¶ 22.

C. Inspectional History and Prior Warnings

Defendants have been repeatedly informed that their conduct violates the FDCA and poses a serious risk to public health. In December 2015, FDA issued a Warning Letter to a CSN affiliate concerning the affiliate's manufacture of an SVF product. SUF ¶ 57. The letter to the affiliate explained that the SVF product being manufactured was a drug and biological product and was not marketed lawfully under the FDCA. SUF ¶ 57. FDA inspected CSCTC's Rancho Mirage facility from July 17 through July 26, 2017 and CSCTC's Beverly Hills facility from July 21 through 27, 2017. SUF ¶ 47. At the end of the inspections, FDA investigators issued lists of specific observations ("Form FDA 483") documenting Defendants' failure to comply with CGMP requirements. *Id.*; *see also* SUF ¶¶ 48-51. Both during and following the July 2017 inspections, Defendants asserted that they were not manufacturing drugs or biological products and thus were not subject to the FDCA. SUF ¶¶ 59, 62. In August 2017, United States Marshals seized five vials of ACAM2000 that Defendants used to prepare their SVF/Vaccinia product. SUF ¶ 60; *see*

also supra note 3. During additional communications with FDA in August and October 2017, Defendants reiterated that they were not subject to the FDCA. SUF ¶ 62.[5]

D. Adverse Medical Events

Evidence of patient harm is not required to establish a violation of the FDCA or to obtain an injunction, but the Government's safety concerns are real. Defendants' use of the vaccinia virus put at risk not only their own patients, but also anyone in close contact with them who could have been infected with the smallpox virus. During FDA's 2017 inspections of CSCTC's facilities, investigators reviewed several records that documented serious adverse events involving the CSCTC products, including:

- On February 6, 2017, a patient with COPD lost consciousness and was hospitalized after being treated with Defendant's SVF product intravenously and via nebulizer at CSCTC Beverly Hills. SUF ¶ 52. The event was not identified as an adverse event by Defendants, yet a notation in the patient's records indicated that in the future, the patient should only receive intravenous SVF and "NO nebulizer." *Id*.

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[5] Although they are not binding and do not have the force and effect of law, FDA has issued several guidances consistently outlining its thinking on many of the matters at issue in this case. *See US Stem Order* at 17-21. These guidances were issued first in draft form and received public notice and comment before being finalized, pursuant to 21 U.S.C § 371(h) and FDA's Good Guidance Practices regulation at 21 C.F.R. § 10.115. The guidances include the following:

- Food & Drug Admin., Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Guidance for Industry, November 2017 (hereinafter, "SSPE Final Guidance"), *available at* https://www.fda.gov/media/89920/download (Last accessed: July 7, 2019);
- Food & Drug Admin., Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff," dated November 2017 and corrected December 2017 (hereinafter "MM Final Guidance"), *available at* https://www.fda.gov/media/109176/download (Last accessed: July 7, 2019);
- Food & Drug Admin., Proposed Approach to Regulation of Cellular and Tissue-Based Products, FDA Dkt. No. 97N 0068 (Feb. 28, 1997) (hereinafter, "1997 Proposed Approach"), *available at* https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM062601.pdf (Last accessed: July 7, 2019).

See also:

- Food & Drug Admin., Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff, Dec. 2014, *available at* https://wayback.archive-it.org/7993/20170721165837/https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/ucm427692.htm (Last accessed: July 7, 2019).

- On April 16, 2016, a patient who received SVF injected through a catheter into the area around the brain at CSCTC Beverly Hills was hospitalized when testing revealed evidence of infection. SUF ¶ 53.
- On March 21, 2016, a patient who received SVF in her knee at CSCTC Beverly Hills reported an infection and being unable to walk for six months. SUF ¶ 54.

Defendants also received reports of adverse events related to SVF products offered by CSN affiliates. SUF ¶ 55. For example, records possessed by Defendants show that a patient who received the SVF product injected into her eyes by a CSN affiliate on or about September 8, 2016, reported a retinal detachment. SUF ¶ 56. Defendants subsequently informed affiliates not to inject the SVF product into patients' eyes.[6] *Id*.

Aside from their products' obvious safety risks, Defendants' marketing gives unsubstantiated hope to people suffering from serious and sometimes life-threatening conditions. Patients who believe Defendants' claims may forgo proven treatments in favor of expending time and money on Defendants' unapproved products, which Defendants have not shown to be safe or effective.

IV. STANDARD FOR SUMMARY JUDGMENT

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "[T]he mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). "An issue is 'genuine' only if there is a sufficient evidentiary basis on which a reasonable fact finder could find for the nonmoving party, and a dispute is 'material' only if it could affect the outcome of the suit under the governing law." *In re Barboza*, 545 F.3d 702, 707 (9th Cir. 2008). However,

[6] A 2017 article in the New England Journal of Medicine discussed the association between adipose-derived SVF products administered to the eyes and blindness. The patients mentioned in the article had been treated by the defendants in *US Stem Cell*, using a similar adipose-derived SVF product as the one at issue here. *See* Ajay E. Kuriyan, et al., *Vision Loss after Intravitreal Injection of Autologous "Stem Cells" for AMD*, 376 NEW ENG. J.MED. 1047, 1050 (Mar. 16, 2017), *available at* http://www.nejm.org/doi/full/10.1056/NEJMoa1609583#t=article (last accessed: July 7, 2019).

"[i]f the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson*, 477 U.S. at 249–50 (internal citations omitted).

V. ARGUMENT

There are no genuine disputes of material fact here. Defendants admit nearly all the relevant facts, and the remainder are beyond dispute. First, the facts show that Defendants' CSCTC products are "drugs" under the FDCA and "biological products" under the PHSA. Second, the record shows that Defendants violate the FDCA by selling the adulterated and misbranded CSCTC products after at least one component of the products traveled in interstate commerce. Third, Defendants cannot excuse their violations as falling within an exception from FDA's HCT/P regulations.[7] Finally, there is no question that Defendants will continue their illegal conduct unless enjoined by this Court.

A. Defendants' CSCTC Products Are Drugs Subject to the FDCA

Defendants admit all the facts necessary to establish that their CSCTC products are drugs within the meaning of the FDCA. As discussed, whether an article is a drug depends on its intended use, which may be shown by how the product is promoted in its labeling and marketing. 21 U.S.C. § 321(g)(1)(B) & (C); 21 C.F.R. § 201.128; *Action on Smoking & Health*, 655 F.2d at 239; *see US Stem Cell Order* at 28-29. The "intended use" of a product refers to the objective intent of the persons legally responsible for its labeling. *United States v. Lane Labs USA, Inc.*, 324 F. Supp. 2d 547, 567 (D.N.J. 2004), *order modified*, 328 F. Supp. 2d 520 (D.N.J. 2004), *aff'd*, 427 F.3d 219 (3d Cir. 2005).

The CSCTC products are "drugs" under the FDCA, both because they are "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and also because they are "intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(B) & (C). Indeed, Defendants promote them to the public to treat a host of serious diseases and conditions in a variety of contexts.

[7] The Government addresses in this section some of the arguments Defendants previously raised in this litigation and to FDA. Although some of those arguments overlap with the affirmative defenses in Defendants' Answer, the Government does not attempt to respond to all of those affirmative defenses in this brief. The Government reserves the right to respond to any affirmative defenses Defendants raise.

Moreover, Defendants admit they use the CSCTC products to address symptoms of neurological, autoimmune, orthopedic, and degenerative medical conditions and diseases, including cancer, arthritis, stroke, amyotrophic lateral sclerosis ("ALS"), MS, macular degeneration, Parkinson's disease, and COPD. SUF ¶ 7. Statements made by Defendants that further establish the intended uses of the CSCTC products—and thus their status as a "drug"—include:

- A CSN website answers the question "Can stem cells treat cancer?" and explains that CSN is involved in "cutting edge clinical trials using stem cells to carry cancer-killing biologic agents deep into cancer tissue that has not responded to conventional therapy." SUF ¶ 37.
- A CSN website lists more than 30 diseases or conditions that CSN is "currently studying," including MS, ALS, cardiomyopathy, lupus, and macular degeneration. SUF ¶ 38.
- A CSCTC brochure entitled "Adipose Stem Cell Therapy and You" that was provided to prospective patients markets "a solution rich with your own stem cells" that "can be deployed to treat a number of degenerative conditions and diseases." SUF ¶ 39. The brochure notes that there have been "reports of improvements with MS, Muscular Dystrophy, Parkinson's, ALS, and stroke." *Id*.
- A videotaped interview of Defendant Lander available to the public promotes SVF "for cancer therapies," arthritis, heart disease, lung disease and interstitial cystitis, and "brain conditions . . . . [by] injecting the cells directly into the brain." SUF ¶ 40.

Because there is no genuine dispute that Defendants' "intended use" of the CSCTC products is to treat, cure, or mitigate a variety of diseases and medical conditions or to affect the structure or function of the body, they are "drugs" under the FDCA. *See* SUF ¶¶ 37-40. Thus, as with other drugs, the CSCTC products are subject to the FDCA's adulteration and misbranding provisions. *See* 21 C.F.R. § 1271.20; Final Registration Rule, 66 Fed. Reg. at 5449, 5456.

B. Defendants Violate the FDCA By Adulterating Their CSCTC Products

To show that Defendants violate 21 U.S.C. § 331(k) by adulterating their CSCTC products, the Government must establish: (1) the CSCTC products are drugs within the meaning of 21 U.S.C. § 321(g)(1)(B) or (C), which has been established *supra*; (2) the CSCTC products are held for sale after one or more of its components have been shipped in interstate commerce; and (3) Defendants cause the CSCTC products to become

adulterated—here, by failing to comply with CGMP.

1. Defendants' CSCTC Products Are Held for Sale After Shipment of One or More of Their Components in Interstate Commerce

Section 331(k) prohibits taking any action with respect to a drug "if such act is done while such article is held for sale . . . after shipment in interstate commerce and results in such article being adulterated or misbranded." 21 U.S.C. § 331(k). A product is "held for sale" if it is used for any purpose other than personal consumption. *United States v. Torigian Labs., Inc.*, 577 F. Supp. 1514, 1521 (E.D.N.Y. 1984), *aff'd*, 751 F.2d 373 (2d Cir. 1984) (unpublished table decision); *see United States v. Diapulse Corp. of Am.*, 514 F.2d 1097, 1098 (2d Cir. 1975); *United States v. Evers*, 643 F.2d 1043, 1050 (5th Cir. 1981) ("A practicing physician may also fall within the bounds of this section. . . . Doctors holding drugs for use in their practice are clearly one part of the distribution process, and doctors may therefore hold drugs for sale within the meaning of [21 U.S.C. § 331(k)]."); *US Stem Cell Order* at 28 n.11. Defendants' CSCTC products are "held for sale" by Defendants because they market and offer their products to patients for commercial purposes other than Defendants' own personal consumption. SUF ¶ 7.

Defendants' CSCTC products also satisfy section 331(k)'s "after shipment in interstate commerce" requirement because at least one component of the CSCTC products (*e.g.*, 0.9% Sodium Chloride Injection, USP) has traveled in interstate commerce. The FDCA defines "drug" to include components of a drug. 21 U.S.C. § 321(g)(1)(D). Courts consistently have interpreted sections 331(k) and 321(g)(1)(D) to mean that the final drug product (here, the CSCTC products) need not have been shipped in interstate commerce in completed form to satisfy the requirement. *See, e.g.*, *Baker v. United States*, 932 F.2d 813, 814-15 (9th Cir. 1991) ("the 'shipment in interstate commerce' requirement is satisfied even when only an ingredient is transported interstate"); *United States v. Dianovin Pharms., Inc.*, 475 F.2d 100, 103 (1st Cir. 1973) ("appellants' use of components shipped in interstate commerce to make vitamin K for injection brought their activities within section 331(k), and conferred jurisdiction to restrain violations thereof upon the

district court"); *Regenerative Scis.*, 741 F.3d at 1320-21; *US Stem Cell Order* at 28 n.11. When one of a drug's components has been shipped in interstate commerce, using that component to manufacture an article of drug that is or becomes adulterated or misbranded violates 21 U.S.C. § 331(k). *Dianovin Pharms.*, 475 F.2d at 103.

Defendants cannot dispute that this element is satisfied. Defendants admit that their preparation and administration of the CSCTC products uses one or more components shipped from outside California. SUF ¶¶ 23-24. Components received include 0.9% Sodium Chloride Injection, USP and 5% Dextrose in Lactated Ringer's Injection, both of which originate outside the State. SUF ¶ 24. Defendants' manufacturing process also involves a collagenase product made in Indiana. *Id*. Vaccinia Vaccine used to manufacture the SVF/Vaccinia product was shipped in interstate commerce from Georgia. SUF ¶ 28. And their expanded SVF product comes from a firm outside of California. SUF ¶ 29. Further, as a general matter, Congress has specified that "the connection with interstate commerce required for jurisdiction" in "any action to enforce the requirements of [the FDCA] respecting a . . . drug . . . shall be presumed to exist." 21 U.S.C. § 379a; *see United States v. Chung's Prods. LP*, 941 F. Supp. 2d 770, 795 (S.D. Tex. 2013). As a result, Defendants' CSCTC products are held for sale after shipment of one or more of their components in interstate commerce.

2. Defendants Adulterate Their CSCTC Products

Under the FDCA, a drug is adulterated if "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with [CGMP] to assure that such drug meets the requirements of [the FDCA] as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C. § 351(a)(2)(B). CGMP regulations establish minimum requirements applicable to drugs, as well as biological products, to ensure that they have the identity, strength, quality, purity, and other attributes necessary for safe and effective use. *See* 21 C.F.R. Parts 210-211 (drugs); 21 C.F.R. Parts 600-680 (additional standards for biological

products). Violation of a single CGMP regulation is sufficient to make a drug adulterated. *See United States v. W. Serum Co.*, 498 F. Supp. 863, 867-68 (D. Ariz. 1980), *aff'd*, 666 F.2d 335 (9th Cir. 1982); *United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1287 (D.P.R. 1992).

When drugs are not manufactured or held in conformance with CGMP, they are adulterated as a matter of law, regardless of whether the products are actually deficient. 21 U.S.C. § 351(a)(2)(B); *John D. Copanos & Sons, Inc. v. FDA*, 854 F.2d 510, 514 (D.C. Cir. 1988) ("Drugs produced in violation of these CGMP regulations are deemed to be adulterated without the agency having to show that they are actually contaminated."); *Regenerative Scis.*, 741 F.3d at 1323 (where "facilities, methods, and controls for processing the [appellants' stem cell product] violated [CGMP], the Mixture is per se adulterated, regardless of any other safety protocols appellants happen to use.").

Defendants do not dispute that their operations fail to comply with CGMP requirements. SUF ¶ 49. The evidence collected by FDA investigators during inspections of CSCTC Rancho Mirage and Beverly Hills facilities in 2017 showed significant CGMP violations. SUF ¶¶ 47-51. For example, FDA investigators observed that CSCTC did not manufacture its CSCTC products under aseptic conditions or properly test them to check for the presence of objectionable microorganisms at either CSCTC facility. *Id.* FDA investigators presented these observations to Defendants Berman and Lander at the close of each inspection. SUF ¶ 47. Because the undisputed evidence shows that Defendants do not comply with CGMP, their CSCTC products are adulterated. *See* 21 U.S.C. § 351(a)(2)(B).

C. Defendants Violate the FDCA by Misbranding the CSCTC Products

Defendants violate 21 U.S.C. § 331(k) by misbranding their CSCTC products. As discussed in Sections A and B.1 of this Argument, the CSCTC products are drugs that are held for sale after shipment of one or more of their components in interstate commerce. They are misbranded under 21 U.S.C. § 352(f)(1) because their labeling lacks adequate directions for use, and under 21 U.S.C. § 353(b)(4) because their labeling does not bear

the "Rx Only" symbol. Moreover, the Defendants' SVF/Vaccinia product is misbranded under 21 U.S.C. § 352(j) because it is dangerous to health.

1. The CSCTC Products are Misbranded Under 21 U.S.C. § 352(f)(1)

A drug is misbranded under the FDCA "unless its labeling bears adequate directions for use" and the drug does not fall within a regulatory exemption from that requirement. 21 U.S.C. § 352(f)(1). The labeling on Defendants' CSCTC products does not bear adequate directions for use for three different reasons, any one of which is sufficient to establish misbranding: (1) the CSCTC products do not bear labeling that contains information required for adequate directions for use, as defined in 21 C.F.R. § 201.5; (2) the CSCTC products are unapproved prescription drugs that are not excepted from labeling regulations requiring directions under which a lay person can use the drug safely; and (3) it is currently impossible to draft adequate directions for use because there is no scientifically valid evidence to show that the CSCTC products are safe or effective for any indication.

a. Defendants' CSCTC Products Do Not Bear Labeling That Contains Information Required for Adequate Directions for Use

Under the relevant regulations, "adequate directions for use" are "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5; *see also United States v. Algon Chem., Inc.*, 879 F.2d 1154, 1156 (3d Cir. 1989) ("Courts have consistently upheld the FDA's interpretation of this provision as requiring adequate directions for use of the drug by a layman."); *United States v. Articles of Drug (Rucker Pharmacal)*, 625 F.2d 665, 673 (5th Cir. 1980) (a "drug's labeling must contain adequate directions for a consumer to engage in self-medication."); *United States v. Two Units, More or Less, of an Article or Device, Consisting of a Power Unit and a Chair*, 49 F.3d 479, 482 (9th Cir. 1994) (medical device is "misbranded if it does not bear adequate directions to enable a layperson to use it safely.").

The misbranding regulations at 21 C.F.R. § 201.5 provide that directions for use are inadequate unless the drug's labeling contains, among other things: quantity of dose,

including the usual quantities for each of the uses for which it is intended and usual quantities for persons of different physical conditions; frequency and duration of administration; time of administration in relation to time of meals, onset of symptoms, and other factors; and route or method of administration. 21 C.F.R. § 201.5; *see also Regenerative Scis.*, 741 F.3d at 1323-24 ("The FDCA also provides that a drug 'shall be deemed to be misbranded' if its label omits certain information"); *Alberty Food Prods. v. United States*, 194 F.2d 463, 464 (9th Cir. 1952) (adequate directions for use must include statement of "the purposes and conditions for which the drug was intended and sufficient information to enable a layman to intelligently and safely attempt self medication").

Defendants admit that they do not label the CSCTC products with indications for use, dosages, or routes of administration. SUF ¶ 22. Thus, the labeling for Defendants' CSCTC products does not include all of the information required by 21 C.F.R. § 201.5. This alone is sufficient to render the CSCTC products misbranded under 21 U.S.C. § 352(f)(1).

b. The CSCTC Products Are Unapproved Prescription Drugs That Are Not Exempted From Labeling Requirements

Defendants' CSCTC products are not only unapproved drugs; they also are unapproved prescription drugs. The FDCA specifies that a drug is a prescription drug if, due to "its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [the drug] is not safe for use except under the supervision of a practitioner licensed by law to administer such drug . . . ." 21 U.S.C. § 353(b)(1)(A); *see United States v. Munoz*, 430 F.3d 1357, 1367 (11th Cir. 2005). Defendants' CSCTC products satisfy this definition in at least two ways. First, they are intended to be administered intravenously or by nebulizer or injection into specific areas of the body. SUF ¶ 8. Medical expertise, licensure, and appropriate training is necessary to administer products by intravenous, subcutaneous, or intramuscular injections. Lapteva Decl. ¶ 40. Because the intended method of using the CSCTC products requires medical training, it is a prescription drug. Lapteva Decl. ¶ 43.

Second, scientific literature documents the harmful effects that may occur as a result of administering products from adipose tissue using routes of administration such as those used for Defendants' CSCTC products. Lapteva Decl. ¶ 40. Those harmful effects include administration site reactions such as swelling, tendonitis, and intra-articular pain, as well as systemic reactions manifested by transient fever, facial flushing and myalgia, and pulmonary embolism. *Id*. The potential for harmful effects means the CSCTC products are not safe for use except under the supervision of a practitioner licensed by law to administer such a drug. Lapteva Decl. ¶¶ 40, 41.

Accordingly, due to the method of their use and potential for harmful effects related to the CSCTC products' administration, Defendants' CSCTC products are prescription drugs. *See* 21 U.S.C. § 353(b)(1)(A); Lapteva Decl. ¶ 43.

The labeling for prescription drugs (like the CSCTC products) cannot, as a matter of law, satisfy the requirement that they bear adequate directions for use by a layperson. A prescription drug, by its nature, may be used safely only under the supervision of a physician. *See* 21 U.S.C. § 353(b)(1); *Articles of Drug (Rucker Pharmacal)*, 625 F.2d at 670. Because prescription drugs can be used safely only at the direction, and under the supervision, of a physician, directions under which the layperson could use a drug safely cannot be written for a prescription drug. *Articles of Drug (Rucker Pharmacal)*, 625 F.2d at 673 (it is not possible to provide a layperson with adequate directions for use for a prescription drug); *United States v. Baxter Healthcare Corp.*, 712 F. Supp. 1352, 1359 (N.D. Ill. 1989), *aff'd*, 901 F.2d 1401 (7th Cir. 1990); *United States v. An Article of Drug . . . Mykocert*, 345 F. Supp. 571, 573 (N.D. Ill. 1972).

As prescription drugs that cannot, by definition, bear adequate directions for use by a layperson, the CSCTC products are per se misbranded unless they qualify for an exemption from section 352(f)(1). *Articles of Drug (Rucker Pharmacal)*, 625 F.2d at 673 ("Since a prescription drug by definition can be used only under a physician's supervision, and is unsuitable for self-medication, such a drug must qualify for a regulatory exemption created by FDA" under section 352(f)); *United States v. Premo Pharm. Labs., Inc.*, 511 F.

Supp. 958, 977 n.23 (D.N.J. 1981) ("A drug is misbranded if it is a prescription drug that is an unapproved new drug, because a prescription drug cannot bear the adequate directions for use required by statute, section 352(f)(1), and the lack of an approved [new drug application] means that there is no FDA exemption from the adequate directions for use requirement") (citations omitted). Defendants do not claim—and cannot meet their burden of showing[8]—that they qualify for such an exemption. *See United States v. 9/1 Kg. Containers*, 854 F.2d 173, 176 (7th Cir. 1988) (claimant bore burden of proof that drugs qualified for exemption to requirement that drug labeling bear adequate directions for use). Thus, the CSCTC products are misbranded under the FDCA for this second reason.

c. It Is Currently Impossible to Draft Adequate Direction for Use for the CSCTC Products

The third basis for determining that the CSCTC products are misbranded is that it is currently impossible to draft adequate directions for use of the CSCTC products because there is no scientifically valid evidence to show that the products are safe or effective for any indication. Adequate directions for use, which include information about, among other things, indications, dosages, and routes of administration, must be based on data derived from well-controlled scientific testing. *See United States v. Undetermined Quantities of Articles of Drug*, 145 F. Supp. 2d 692, 702 (D. Md. 2001) ("Essentially, in the absence of investigations or clinical data demonstrating the safety and efficacy of the drugs, there can be no adequate instruction for their safe use."); *United States v. Cole*, 84 F. Supp.3d 1159, 1169 (D. Or. 2015) (Adequate directions for use, which "include indications, contraindications, dosages, routes of administration, warnings, side effects,

[8] For example, 21 C.F.R. § 201.115(a) permits a "new drug" to be exempt from section 352(f)(1) "[t]o the extent . . . such exemption is claimed in an approved" new drug application. Defendants' CSCTC products are new drugs. *See* 21 U.S.C. § 321(p)(1); SUF ¶¶ 43-44; *Weinberger v. Hynson, Westcott, & Dunning, Inc.*, 412 U.S. 609, 629-30 (1973) (in the absence of "any evidence of adequate and well-controlled investigation supporting the efficacy of [a drug], *a fortiori* [the drug] would be a 'new drug' subject to the provisions of the [FDCA]"). As unapproved new drugs (SUF ¶¶ 34-36), CSCTC products cannot qualify for the exemption in 21 C.F.R. § 201.115. *See Articles of Drug (Rucker Pharmacal)*, 625 F.2d at 675. The CSCTC products also fail to qualify for the exemption for prescription drugs for human use in 21 C.F.R. § 201.100 because their label does not bear information required under 21 C.F.R. §§ 201.100(b) and (c)(1), among other things. *See* SUF ¶ 22; Lapteva Decl. ¶¶ 48-50.

and necessary collateral measures, must be premised on clinical data derived from scientifically controlled investigation—the sort of investigation required for FDA approval."). Because no well-controlled studies have been conducted on Defendants' CSCTC products, there is no scientifically valid evidence to show the CSCTC products are safe or effective for any indication, or on which to base the directions for use. *See* SUF ¶ 43. As a result, Defendants have not offered—and cannot offer—"adequate directions for use" for the "safe[]" use of their CSCTC products within the meaning of 21 C.F.R. § 201.5, and the CSCTC products are, thus, misbranded under 21 U.S.C. § 352(f)(1). *See Cole*, 84 F. Supp.3d at 1169.

2. The CSCTC Products are Misbranded Under 21 U.S.C. § 353(b)(4)

The FDCA requires prescription drugs to bear the symbol "Rx only." 21 U.S.C. § 353(b)(4). As discussed above, the CSCTC products are plainly prescription drugs because of the method for their use and potential for harmful effects related to their administration. SUF ¶ 46; Lapteva Decl. ¶ 40. Additionally, Defendants admit that they do not label their products "Rx only." SUF ¶ 22. As such, their products are misbranded under 21 U.S.C. § 353(b)(4). *See Regenerative Scis.*, 741 F.3d at 1324.

3. The Defendants' SVF/Vaccinia Product is Misbranded Under 21 U.S.C. § 352(j)

In addition to being misbranded under 21 U.S.C. §§ 352(f)(1), and 353(b)(4), Defendants' SVF/Vaccinia product is misbranded under 21 U.S.C. § 352(j) because it is "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof." To prove a violation of 21 U.S.C. § 352(j), the Government need not show that the product is dangerous to the health of all who take it in the dosage and for the duration prescribed or recommended. It need only show that the drug is "dangerous to the public health at large if used as recommended by its vendors." *See United States v. 62 Packages . . . of Marmola Prescription Tablets*, 142 F.2d 107, 110 (7th Cir. 1944). A drug can be dangerous to health when used as labeled for a variety of reasons, including where the drug's labeling

fails to contain adequate warnings of potential side effects. *United States v. Lanpar Co.*, 293 F. Supp. 147, 154 (N.D. Tex. 1968) (drug for obesity failed to warn about side effects).

Defendants' SVF/Vaccinia product—which Defendants have used purportedly to treat cancer patients—is a danger to health. The specific vaccine used by Defendants, ACAM2000, is an FDA-licensed product with a "black box warning" designed to warn of serious or life-threatening product risk, including swelling of the heart tissues, brain, or spinal cord. *See* 21 C.F.R. § 201.57(c)(l); Fink Decl. at ¶ 10. ACAM2000 is not indicated for the treatment of cancer patients who may not have normal immune systems. *Id*. at ¶¶ 14-18. Additionally, although the vaccine should be administered using a bifurcated needle that pricks the skin, Defendants administered their SVF/Vaccinia product intravenously or directly into patients' tumors. *Id*. at ¶ 16. The SVF/Vaccinia product also contained amounts of the vaccine that greatly exceeded the vaccine's labeled dosage. *Id*. at ¶ 17.

Given these circumstances, the SVF/Vaccinia product is a danger to health in the manner used, and it is misbranded under 21 C.F.R. § 352(j). *Id.* at ¶ 19. Moreover, the product poses an additional risk to the public at large since several patients who received it developed skin lesions that can shed live, infectious vaccinia virus to people in contact with those patients. *Id*. at ¶ 18. *See also* Lapteva Decl. at ¶ 52. The safety concerns associated with Defendants' SVF/Vaccinia product were recognized by Defendants' own expert witness, Lola M. Reid, Ph.D., who conceded that adding a vaccine to SVF would make her "nervous" because "there are many things that can happen." *See* SUF ¶ 67.

D. Defendants Violate 21 U.S.C. § 331(c) With Respect to Their Expanded SVF Product

The FDCA prohibits "the receipt in interstate commerce of any . . . drug . . . that is . . . misbranded, and the delivery or proffered delivery thereof for pay or otherwise." 21 U.S.C. § 331(c). To establish a violation of section 331(c), the Government must show: (1) that Defendants received a drug in interstate commerce; (2) the drug was misbranded when it was received by Defendants; and (3) that the drug was thereafter delivered or

proffered for delivery for pay or otherwise. All of these elements are evident.

As discussed above, CSCTC's expanded SVF product is a drug under the FDCA that Defendants receive from a firm outside of California. *See, supra,* Sections A and B.1 of the Argument. The expanded SVF is misbranded because it lacks adequate directions for use. *See, supra*, Section C of the Argument. Finally, Defendants deliver the expanded SVF to their patients who pay them for their services. SUF ¶¶ 29, 25. Defendants have thus violated the FDCA, 21 U.S.C. § 331(c), with respect to their expanded SVF product.

E. The "Same Surgical Procedure" Exception Does Not Apply, Nor Do the CSCTC Products Qualify as "361 HCT/Ps"

Defendants have argued that the FDCA's prohibitions and its adulteration and misbranding provisions do not apply to them and their products. Defendants claim that they qualify for the "same surgical procedure" exception at 21 C.F.R. § 1271.15(b). They also have suggested that their CSCTC products meet the criteria in 21 C.F.R. § 1271.10(a) for regulation solely under section 361 of the PHSA and the regulations in Part 1271. Like in *United States v. US Stem Cell Clinic*, and for the reasons explained below, Defendants cannot meet their burden to show that either provision applies. *See Regenerative Scis.*, 741 F.3d at 1322 ("appellants ultimately bear the burden of establishing that [21 C.F.R. § 1271.10(a)] applies").

1. The Same Surgical Procedure Exception at 21 C.F.R. § 1271.15(b) Does Not Apply

Defendants have asserted that their CSCTC products should be excepted from the FDCA's public health protections because they are performing surgery that involves the patient's own cells. SUF ¶¶ 39, 59, 62, 68. Defendants reference what is known as the "same surgical procedure" exception, which provides:

> You are not required to comply with the requirements of [21 C.F.R. Part 1271] if you are an establishment that removes HCT/P's from an individual and implants *such HCT/P's* into the same individual during the same surgical procedure.

21 C.F.R. § 1271.15(b) (emphasis added).

The same surgical procedure exception does not apply here because the CSCTC

products—comprised of cells, saline, and perhaps other components left behind from the manufacturing process—implanted into patients is *not* the HCT/P that Defendants remove from patients. The same surgical procedure exception is specific to implantation of "such HCT/P's," a phrase that describes the antecedent HCT/P's "remove[d] . . . from an individual." By the text of the regulation, the same surgical procedure exception thus applies only where an HCT/P is removed from a patient and then "such HCT/P" is implanted back into the patient. If, as here, the removed HCT/P is transformed via processing so that it is no longer "such HCT/P," then the exception does not apply. In other words, "such HCT/P's" must mean HCT/P's in the form removed from the body. *US Stem Cell Order* at 12 (finding "the text of § 1271.15(b) unambiguously supports the FDA's interpretation, that 'such HCT/P's' refers to the antecedent HCT/P removed from the patient in its original form."). This construction is the only plausible one, as any alternate construction would render the word "such" meaningless. *See, e.g.*, *United States v. Bowen*, 100 U.S. (10 Otto) 508, 512 (1879) (reading the statutory phrase "all such pensioners" to refer to the subset of pensioners previously referenced in the statutory text, since construing the phrase otherwise would treat the word "such" as surplusage); *First Charter Financial Corp. v. United States*, 669 F.2d 1342, 1350 (9th Cir. 1982) (citation omitted) ("Construction which gives effect to all of the words of a statute or regulation is preferred over an interpretation which renders some of the statute or regulation ineffective."); *United States v. Canals-Jimenez*, 943 F.2d 1284, 1287 (11th Cir. 1991) ("A basic premise of statutory construction is that a statute is to be interpreted so that no words shall be discarded as being meaningless, redundant, or mere surplusage.").[9]

[9] The Government construes the phrase "such HCT/Ps" consistent with the plain language, the structure and regulatory history of Part 1271, and Congressional and regulatory intent, as courts must. *See Kisor v. Wilkie*, 18-15, 2019 WL 2605554, at *8 (U.S. June 26, 2019) (requiring courts to exhaust all traditional tools of construction before concluding that a rule is ambiguous). But even if this Court were to find the phrase ambiguous, FDA's interpretation should be accorded substantial deference because its interpretation "necessarily require[s] significant expertise and entail[s] the exercise of judgment grounded in policy concerns." *See Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994), *quoting Pauley*

While very limited processing steps, such as rinsing, cleansing, sizing, or shaping, may allow an HCT/P to remain in its original form, the adipose tissue that Defendants remove from patients undergoes a dramatic transformation into something other than "such HCT/P" as was removed from the individual. *See* SUF ¶¶ 15-16; Yong Decl. ¶¶ 27, 33. Adipose tissue—the HCT/P removed from patients—is a structural tissue composed of cells surrounded by a reticular fiber network and interspersed small blood vessels. SUF ¶¶ 11-13; Yong Dec. ¶ 36. Defendants intentionally break down that adipose tissue through enzymatic digestion and isolate cellular components. SUF ¶ 10. The enzyme digests much of the tissue by disrupting and digesting the reinforced basement membrane to dissociate the cellular contents of the adipose tissue. SUF ¶ 66. What remains of the adipose tissue following Defendants' enzymatic digestion, filtration, centrifugation, and other processing cannot be considered "tissue" at all. SUF ¶¶ 18-20. Rather, the organized structure of the adipose tissue is destroyed, and all that remains is a liquified mixture of cells and cell debris suspended in a saline solution. *See* SUF ¶¶ 16-19, 66. The HCT/P that Defendants remove from patients is thus not the HCT/P that is later implanted, *see* Yong Decl. ¶¶ 27-33, and is accordingly not "such HCT/P's" within the meaning of 21 C.F.R. § 1271.15(b). As a result, the same surgical procedure exception cannot apply. *See also* Yong Decl. ¶ 34.

2. Defendants' CSCTC Products Fail to Meet All of the Criteria in 21 C.F.R § 1271.10(a) for Regulation Solely Under Section 361 of the PHSA

FDCA requirements do not apply to an HCT/P that meets the criteria in 21 C.F.R. § 1271.10(a), which is instead regulated solely under section 361 of the PHSA and the regulations in 21 C.F.R. Part 1271. A "Section 361" HCT/P must meet all four of the

v. BethEnergy Mines, Inc., 501 U.S. 680, 697 (1991); *see also United States v. Regenerative Scis., LLC*, 878 F. Supp. 2d 248, 258 (D.D.C. 2012); *Kisor*, 2019 WL 2605554, at *10. FDA's interpretation of "such HCT/P's" is documented in the non-binding SSPE Final Guidance, which underwent a public notice and comment period before being finalized pursuant to 21 U.S.C. § 371(h) and 21 C.F.R. §10.115. That guidance states, "An HCT/P remains 'such HCT/P' when it is in its original form. Generally, the only processing steps that will allow an HCT/P to remain 'such HCT/P' are rinsing, cleansing, sizing, and shaping." SSPE Final Guidance at 5.

regulatory criteria.[10] 21 C.F.R. §§ 1271.10(a) & 1271.20. These include that the HCT/P must not be more than "minimally manipulated" and must be "intended for homologous use only." 21 C.F.R. § 1271.10(a)(1)-(2); 21 C.F.R. § 1271.20; 66 Fed. Reg. at 5456.[11] As with the same surgical procedure exception, Defendants cannot meet their burden of demonstrating that their CSCTC products satisfy these criteria. *See Regenerative Scis.*, 741 F.3d at 1322.

a. Defendants' CSCTC Products Are More than Minimally Manipulated

Defendants' CSCTC products are more than minimally manipulated. *See* 21 C.F.R. § 1271.10(a)(1). In defining "minimal manipulation," the Part 1271 regulations distinguish between "structural tissue" and "cells or nonstructural tissues." 21 C.F.R. § 1271.3(f). As noted above, the adipose tissue Defendants recover from patients is structural tissue. SUF ¶¶ 11, 65; Yong Decl. ¶ 36. Adipose tissue is comprised of cells surrounded by a reticular fiber network and interspersed small blood vessels, divided into lobes and lobules by connective tissue septa. SUF ¶ 65. For such structural tissue, "minimal manipulation" means "processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement." 21 C.F.R. § 1271.3(f)(1).

Defendants' transformation of adipose tissue into the CSCTC products falls outside this definition. Defendants break down adipose tissue with enzymatic digestion to isolate

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[10] Because the CSCTC products do not meet the criteria at 21 C.F.R. § 1271.10(a)(1) or (a)(2) for the reasons described, it is unnecessary to further discuss the remaining criteria at 21 C.F.R. § 1271.10(a)(3) and (a)(4). Nevertheless, Defendants' SVF/Vaccinia product clearly fails to satisfy the criteria at 21 C.F.R. § 1271.10(a)(3), because the product combines an HCT/P with "another article," namely the vaccine. *See also* Yong Decl. ¶¶ 45-46.

[11] In promulgating the 21 C.F.R. Part 1271 regulations, FDA was concerned with preventing the transmission of communicable diseases, understanding necessary processing controls (*e.g.*, to prevent contamination that could result in an unsafe or ineffective product), preserving product integrity and function, and ensuring clinical safety and effectiveness. 1997 Proposed Approach at 9. FDA explained that clinical safety and effectiveness concerns depend in part on the extent of manipulation of the cells or tissues. *Id.* at 11. For example, the agency noted, *inter alia*, that "[i]mproper handling . . . can allow cells or tissues to become contaminated (e.g., bacterial contamination during collection, processing, storage, or transplantation, or cross contamination from other contaminated tissues)." *Id.* at 15.

cellular components (*i.e.*, SVF). SUF ¶¶ 10-18. By isolating and removing the adipocytes and all of the structural components from adipose tissue, Defendants alter the original relevant characteristics relating to the tissue's utility to provide cushioning and support, which is essential to the tissue's utility for reconstruction, repair, or replacement. SUF ¶ 15; Yong Decl. ¶¶ 38-39. Unlike adipose tissue, SVF does not provide cushioning and support. SUF ¶ 19, Yong Decl. ¶¶ 38-39. Indeed, in processing SVF from adipose tissue, Defendants deliberately eliminate such characteristics by breaking down the adipose tissue's extracellular matrix and removing the adipocytes. *See* SUF ¶¶ 10, 16-18. By any measure, this wholesale change to the original tissue constitutes far more than "minimal manipulation" for structural tissue. *See* Yong Decl. ¶¶ 38-39. Defendants' failure to meet this criterion is alone sufficient to render the regulatory scheme in 21 C.F.R. § 1271.10(a) inapplicable.

b. Defendants' CSCTC Products Are Not Intended for Homologous Use Only

Defendants' CSCTC products are also not "intended for homologous use only." *See* 21 C.F.R. § 1271.10(a)(2). "Homologous use" means "the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that *performs the same basic function or functions* in the recipient as in the donor." 21 C.F.R. § 1271.3(c) (emphasis added).[12] Whether an HCT/P is intended to perform the same basic function or functions in the recipient as in the donor is determined from the manufacturer's "labeling, advertising, or other indications of . . . objective intent." 21 C.F.R. §§ 1271.3(c) & 1271.10(a)(2); *see US Stem Cell Order* at 27.

As described above, the CSCTC products at issue are not intended to perform the same basic function of the adipose tissue recovered from those patients. *See, supra*, Sections D.1 and D.2.a of the Argument; *see also* Yong Decl. ¶¶ 42-44. The basic function

[12] The homologous use requirement reflects the fact that there are "increased safety and effectiveness concerns for HCT/Ps that are intended for a non-homologous use, because there is less basis on which to predict the product's behavior, whereas HCT/Ps for homologous use can reasonably be expected to function appropriately (assuming all of the other criteria are also met)." *See* MM Final Guidance at 4 (citing 1997 Proposed Approach at 19).

of adipose tissue is to provide cushioning and support, such as for skin and organs. SUF ¶¶ 11, 14; *see also* Yong Decl. ¶ 41. Defendants do not promote the CSCTC products for cushioning, support, or anything similar to it. Rather, they market their product as a treatment for a remarkably broad array of serious diseases and conditions such as cancer, arthritis, stroke, ALS, MS, macular degeneration, Parkinson's disease, and COPD. SUF ¶ 7. Such uses bear no resemblance to any basic function of adipose tissue. *See* Yong Decl. ¶ 44; *US Stem Cell Order* at 27.

In addition to failing these criteria, the CSCTC products are not proven treatments for any disease or condition and have not generally been recognized as safe or effective for any such use. SUF ¶ 44. That absence of proof of safety and effectiveness is another "meaningful indicator" that regulation of the product as a section 361 HCT/P "is not sufficient." *See* Final Registration Rule, 66 Fed. Reg. at 5458 ("[P]romotion of an HCT/P for an unproven therapeutic use, such as curing cancer, would clearly make it inappropriate to regulate the HCT/P solely under 361 of the [PHSA] and the regulations that will be in part 1271.").[13]

Defendants subject the adipose tissue they recover to processing that far exceeds minimal manipulation, and they then promote their CSCTC products for uses that bear no resemblance to the function of adipose tissue before it was recovered. The CSCTC products thus meet neither the "minimally manipulated" nor the "homologous use only" criteria under 21 C.F.R. § 1271.10(a). They are not Section 361 HCT/Ps, but rather they are drugs and biological products subject to the FDCA's adulteration and misbranding provisions. *See* 21 C.F.R. § 1271.20; Final Registration Rule, 66 Fed. Reg. at 5458.[14]

[13] To the extent Defendants argue that their "research" will develop data that will help Defendants understand the safety or effectiveness of their product, the FDCA does not permit such experimentation without an IND in effect. *See* 21 U.S.C. § 355(i); 21 C.F.R. § 312.2(a). Defendants concede that they do not have an IND in effect for their CSCTC products. SUF ¶¶ 34-36.

[14] This is clear on the evidence and the plain text of the regulations discussed above, but even if it were not, FDA's conclusions in this regard (*see* MM Final Guidance) would be entitled to "substantial deference." *Thomas Jefferson Univ.*, 512 U.S. at 512; *see also Regenerative Scis.*, 878 F. Supp. 2d at 258 (D.D.C. 2012); *US Stem Cell Order* at 14-20.

F. A Permanent Injunction is Required to Stop the Defendants' FDCA Violations

1. Legal Standard

Under 21 U.S.C. § 332(a), district courts have jurisdiction to enjoin violations of the FDCA. *United States v. Organic Pastures Dairy Co.*, 708 F. Supp. 2d 1005, 1011 (E.D. Cal. 2010). The FDCA's injunctive power should be exercised in light of its purpose to protect the public health, *see United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969), and is appropriate when the United States establishes that the defendant has violated the applicable statute and that there exists "some cognizable danger of recurrent violation." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *United States v. Rhody Dairy LLC*, 812 F. Supp. 2d 1239, 1245-46 (W.D. Wash. 2011). The probability of future violations may be inferred from past unlawful conduct. *See United States v. Laerdal Mfg. Corp.*, 73 F.3d 852, 857 (9th Cir. 1995) (*citing S.E.C. v. Koracorp Indus., Inc.*, 575 F.2d 692, 698 (9th Cir. 1978)); *United States v. Odessa Union Warehouse Coop*, 833 F.2d 172, 176 (9th Cir. 1987); *Organic Pastures*, 708 F. Supp. 2d at 1012. Once the United States establishes the existence of the statutory violation, the burden shifts to the defendants to show that "there is no reasonable expectation that the wrong will be repeated." *W.T. Grant Co.*, 345 U.S. at 633 (citation and quotation marks omitted). Accordingly, "[a] district court may issue an injunction if it concludes that the injunction is necessary to prevent future violations." *United States v. Articles of Drug*, 825 F.2d 1238, 1248 (8th Cir. 1987) (internal citations omitted).[15]

[15] Where, as here, the United States seeks an injunction authorized by statute, it need not prove irreparable harm because harm is presumed when the statute is violated. *Odessa*, 833 F.2d at 176 (internal citations omitted). Although in *United States v. Nutri-Cology*, 982 F.2d 394, 398 (9th Cir. 1992) ("*Nutricology III*"), the Ninth Circuit held that in a statutory injunction case in which the government makes merely a "colorable evidentiary showing" of a violation of the FDCA, the government bears a greater burden of establishing the possibility of irreparable injury, this standard does not apply here, because the Government's evidence reflects far more than merely a "colorable evidentiary showing." But even if the Court concluded otherwise, injunctive relief is still warranted under the *Nutri-cology* standard, because the Government has shown the "actual harm threatened or caused by [D]efendants' products." *See United States v. Nutri-Cology, Inc.*, 1991 WL 1092506, at *2-3 (N.D. Cal. July 19, 1991) ("*Nutricology II*"); *see also United States v. Nutri-Cology, Inc.*, 1991 WL 1078202, at *6 (N.D. Cal. May 23, 1991) ("*Nutricology I*"), *aff'd*, 982 F.2d at 398.

Both corporations and individuals may be found liable for violations of the FDCA. The Supreme Court has held that the FDCA "imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur." *United States v. Park*, 421 U.S. 658, 672 (1975). To establish individual liability under the FDCA, the Government need only show that the defendants "had, by reason of [their] position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that [they] failed to do so." *Park*, 421 U.S. at 673-74; *see also United States v. Gel Spice Co.*, 601 F. Supp. 1205, 1211-12 (E.D.N.Y. 1984).

2. Defendants Violate the FDCA and Will Continue to Violate the FDCA Unless Enjoined

As shown above, Defendants violate the FDCA by causing the adulteration and misbranding of drugs while held for sale after shipment of one or more of their components in interstate commerce. *See, supra*, Sections A, B, and C of the Argument. An injunction is necessary to bring Defendants into compliance with the law and to prevent future violations.

Defendants know that their CSCTC products and conduct violate the FDCA. *See, supra*, Section C of the Statement of Facts. Yet they continue to flout the law and market the CSCTC products as beneficial for patients with serious diseases and conditions, despite lacking proof of their safety or effectiveness. Rather than comply with the law, Defendants continue to claim that the law does not apply to them. Defendants' pattern of violative conduct and insistence that they need not follow the law leaves no doubt that they will continue to violate the FDCA absent an injunction.

The two individual defendants should be enjoined along with the corporate entities. Defendants Berman and Lander are the co-owners and Co-Medical Directors of CSCTC and are the most responsible individuals at CSCTC's facilities in Beverly Hills and Rancho Mirage, California. SUF ¶¶ 3-4. They also are the co-owners and medical directors of CSN. *Id*. They have participated in FDA inspections of their firms and argued extensively

that their operations are beyond FDA's reach. SUF ¶¶ 47, 59, 62.

The risks posed by Defendants' violations, as guided by Defendants Berman and Lander, underscore the need for injunctive relief. Defendants manufacture experimental drugs and biological products in a manner that do not comply with CGMP, thereby posing significant risks to the consumers who receive them. *See, e.g.*, SUF ¶¶ 48-51. The drugs themselves have not been subjected to any adequate and well-controlled clinical trials. SUF ¶¶ 43-44. Therefore, they have not been shown to be safe and effective, through valid scientific evidence, for the treatment of *any* disease or condition, much less the serious diseases and conditions for which Defendants promote their use. *Id.*; *see also* SUF ¶ 7. Indeed, as discussed above, significant adverse medical events have been reported following administration of Defendants' CSCTC products. SUF ¶¶ 52-56. These adverse events, known risks, and FDA warnings have not stopped Defendants' illegal conduct. An injunction is necessary.

VI. CONCLUSION

Defendants' admissions and the uncontested evidence accompanying this motion show there is no genuine dispute of material fact. Defendants violate well-established law, and they endanger the public by manufacturing adulterated and misbranded experimental drugs. Consistent with the recent decision by the United States District Court for the Southern District of Florida in *United States v. US Stem Cell Clinic*, the Government requests that this Court grant summary judgment and permanently enjoin Defendants from causing the adulteration and misbranding of their drugs, and receiving and delivering their misbranded drugs, in violation of the FDCA.

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CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of July 2019, I electronically filed a true and correct copy of the foregoing PLAINTIFF'S NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT, and PLAINTIFF'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFF'S NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT, through the Court's CM/ECF system, which will send a notice of electronic filing to the following counsel of record listed below:

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